

REMARKS

Favorable reconsideration of this application in the light of the amendments and the following remarks is respectfully requested. Claims 1 to 20 are pending in this application.

Specification

The abstract was objected to as containing legal phraseology (means). Accordingly, the abstract has been amended to delete the word "means."

Claim Rejections Under 35 U.S.C. §103

Claims 1-6, 8, 9 and 11-20 stand rejected under 35 U.S.C. §103(a) as being obvious over a combination of Braithwaite (WO/9316748), Kimball et al. (U.S. patent 5944660, hereinafter Kimball), Barnes (International Application WO 00/12163) and Savolainen-Des (U.S. Patent 389570, hereinafter Savolainen).

Claim 1 is directed toward an inhaler which includes a medicament reservoir means "coated on the outer walls, such that the reservoir means is substantially sealed in the coating and is rendered moisture proof."

Kimball is Nonanalogous Art

Kimball is not analogous art and cannot be relied on as a reference under 35 U.S.C. §103. The claims are directed to an inhaler which includes a medicament reservoir means. Kimball neither addresses nor suggests an inhaler, but rather is directed towards an electronic cartridge assembly for sensing characteristics of a sample fluid, such as blood (see Kimball at the abstract and col. 1, lines 7-11). A person skilled in the art of inhalation would have no motivation to look at the cartridge assembly disclosed in Kimball. "In determining the relevant art ... one looks at the nature of the problem confronting the inventor." *Orthopedic Company, Inc. v. United States*, 217 USPQ 193, 196-197 (Fed. Cir. 1983). More particularly, Applicant had to devise a reservoir that keeps stored medicament dry, as opposed to protecting, in Kimball, electronic circuitry from moisture (see Kimball at col. 7, lines 59-67). Given the requirements of the problem, Applicants submit that Kimball's sensor would not have been within the inhaler

art. Accordingly, it is improper to combine Kimball with Braithwaite, Barnes and Savolainen. For this reason, claim 1 should be allowed.

Even if Kimball is Considered With the Other References, Applicant's Invention Would Have Been Nonobvious

As pointed out by the Examiner, Braithwaite fails to disclose an inhaler device with a moisture-resistant coating that is coated on the outer walls of the medicament reservoir such that the reservoir is substantially sealed and rendered moisture proof.

Regarding *Barnes*, the Examiner suggests that this document discloses the coating of various inhaler surfaces with parylene. However, the Examiner has overlooked the fact that the purpose of the coating in Barnes has nothing to do with protecting the contents of the inhaler from moisture. Instead, it is to prevent deposition of drug material on those surfaces. See, for instance, *Barnes* page 1, line 32 et seq:

"A problem with all such drug delivery devices is that deposition of the medicament, or a solid component from a suspension of a particulate product in a liquid propellant, on the internal surfaces and other components of the devices occurs after a number of operation cycles and/or storage. This can lead to reduced efficiency of operation of the device and of the resulting treatment in that deposition of the product reduces the amount of active drug available to be dispensed."

and page 7, lines 16-22:

"It has been found that coating the surface of component parts with Parylene significantly reduces the deposition of active drugs on the relevant surfaces due to factors such as high conformity, absence of pinholes and coefficients of static and dynamic friction between 0.25 and 0.35 giving good friction reduction."

Also, in *Barnes* the components to which the Parylene coating is applied are those components

"... which come into contact with medicament during storage or dispensing"

(see, for instance, *Barnes* Claim 1).

Barnes is not concerned at all with the prevention of moisture ingress into his medicament reservoir (the pressurised container 12), but only with inhibiting the deposition of medicament on surfaces of the inhaler that the medicament contacts during storage and external surfaces that the medicament contacts after the medicament has been dispensed from the reservoir.

According to the examiner, *Savolainen* shows that it was known to provide a moisture-resistant "cover" for a powder inhaler. This is true, but the "cover" in this case has the form of a casing (presumably of injection-moulded plastic) within which the inhaler is stored, and from which it would have to be removed every time it is used. Such a cover can hardly be considered to be suggestive of a "coating" that is "coated on the outer walls" of a medicament reservoir, as is presently claimed. The cover of *Savolainen* will generally inhibit ingress of moisture into the inhaler device, at least so long as the cover is closed. This is potentially beneficial, as any build-up of moisture within the device may exacerbate the problem of medicament deposition addressed by *Barnes*. However, *Savolainen*'s cover cannot in any way be considered to "seal" the medicament reservoir from moisture ingress, particularly as the inhaler would have to be removed from the cover prior to every use of the inhaler, whereupon the reservoir would have no moisture-proofing protection whatsoever.

Of the four prior art references required by the examiner to construct his argument of obviousness, the three that are drawn from a technical field that is relevant to the present invention thus show only that:

- inhalers of the general type that are improved by the present invention were known (Braithwaite);
- the general desirability of inhibiting moisture ingress into an inhaler was known (*Savolainen*);
- coating of certain parts of an inhaler for inhibiting deposition of medicament on the surfaces of those parts was also known (*Barnes*).

What is not apparent from these references is that the external surfaces of the medicament reservoir could be coated in order to seal the reservoir and render it moisture-proof.

In order to complete the argument for obviousness, the Examiner resorts to a reference from a completely different technical field, i.e., *Kimball*. As described above, *Kimball* is concerned with devices for analyzing characteristics of a sample fluid (eg blood). This is not a field to which those skilled in the art of inhalation devices would turn. However, even if the person skilled in the art were to turn to *Kimball*, he would not be led to the present invention. *Kimball* discloses a cartridge assembly that contains an electronic sub-assembly 16 held within a housing that is made up of a lower housing 14 and a cover 12.

At column 7, lines 59-67, *Kimball* describes how the cartridge assembly can be rendered substantially moisture-resistant

"... by coating the electronic circuit assembly 16 with polymeric material ..."

(emphasis added)

The electronic circuit assembly 16 is positioned within the housing 14 of the cartridge assembly 10 (see *Kimball* at Fig. 1). Thus, in *Kimball*, it is the contents of the cartridge assembly housing that are coated in order to create moisture resistance. It is not the case that *Kimball* proposes coating his housing in order to seal the housing and to prevent moisture ingress into the housing.

Clearly, in an inhaler device it is not possible to polymer-coat the contents of the medicament reservoir (the medicament itself). Thus, the teaching of *Kimball* (even if those skilled in the art of inhalation devices were motivated to refer to *Kimball*, which for the reasons we have given we deny) cannot be applied to an inhaler device. Hence, combination of *Kimball* with the other prior art references does not lead those skilled in the art to the present invention.

Thus claim 1 would not have been obvious in light of the combination of the cited art. Claims 1- 8, 9 and 11-20 all of which ultimately depend from claim 1, would also

not have been obvious for the same reasons as discussed above with claim 1, and is further allowable in view of the additional limitations set forth therein.

Claim 7 stands rejected under 35 U.S.C. §103(a) as being obvious over a combination of Braithwaite, Kimball, Barnes, Savolainen-Des and further in view of Kawata (U.S. patent 3798054). Claim 10 stands rejected under 35 U.S.C. §103(a) as being obvious over a combination of Braithwaite, Kimball, Barnes, Savolainen-Des and further in view of Taylor (U.S. patent 5067491).

As stated above, neither Braithwaite, Kimball, Barnes, Savolainen-Des teach or suggest a medicament reservoir means coated on the outer walls, such that the reservoir means is substantially sealed in the coating and is rendered moisture proof, as required by claim 7. Kawata or Taylor also fail to teach or suggest such a limitation.

Kawata discloses sugar coating of tablets intended for oral ingestion. It would not be obvious to those skilled in the art of inhalation device design that such an approach could be applied to the coating of the surfaces of such devices. Nor would it be obvious to those skilled in the art that such a coating would be effective in sealing a medicament reservoir in the manner presently claimed.

Taylor discloses a implantable biomedical device with a Parylene coating. However, the purpose of the coating is to protect the device from deleterious effects of liquid samples (body fluids such as blood) with which the device comes into contact. *Taylor* neither teaches nor suggests preventing long-term ingress into a medicament reservoir of an inhaler device of atmospheric moisture.

Since none of the cited references teach a medicament reservoir means coated on the outer walls, such that the reservoir means is substantially sealed in the coating and is rendered moisture proof, as required by claims 7 and 10, claims 7 and 10 are deemed nonobvious over any combination of these references.

Conclusion

It is believed that the application is now in order for allowance and Applicants respectfully request that a notice of allowance be issued. If any additional extensions are required, applicant hereby petitions for same and requests that any extension or other fee required for timely consideration of this application be charged to Deposit Account No.

19-4972. The Applicants' representative requests the courtesy of a telephone interview, if the Examiner believes such would expedite the prosecution of the application.

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Respectfully submitted,



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